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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,308	09/16/2003	Robert Sutherland	005513P017	4329

7590 12/29/2006  
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EXAMINER
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REED, LYNN D

ART UNIT	PAPER NUMBER
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2112

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/29/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/664,308

Applicant(s)

SUTHERLAND ET AL.

Examiner

Lynn D. Reed

Art Unit

2112

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>09/16/2003 &amp; 11/10/2003</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Specification*

1. The abstract of the disclosure is objected to because of the phrase ‘imagable marker properties’ in the second and third sentence of the abstract. This phrase is not clear because there is not any structure. The word imagable is spelled incorrectly. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities: In paragraph [0052] the word examples should be example. In paragraph [0056] sensor is spelled incorrectly. In paragraph [0061] the number of the sensor device disagrees with figures 2A and 2B. Throughout the specification (e.g. [0045], [0050]) you are not consistent with the numbers used for the markers and marker seeds. In paragraph [0066] sensor is spelled incorrectly. In paragraph [0069] the number of the imager is incorrect. In line 14 of paragraph [0069] the number for the sensor device is incorrect. Throughout the specification the meaning of the phrases ‘imagable properties’, ‘imaging properties’, ‘multiple imaging properties’ and ‘imagable marker properties’ are not clear and you need to include more information to clearly define what these phrases mean and their relationship to the sensor. Throughout the specification imagable is spelled incorrectly. Appropriate correction is required.

### *Drawings*

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character “660” has been used to designate both correlate identified markers in with 3d reference positions and projection of markers. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application.

Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to under 37 CFR 1.83(a) because they fail to show 1330 and 1340 in figure 12 as described in the specification in paragraph [0099]. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Objections***

3. Applicant is advised that should claim 21 be found allowable, claim 22 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 1,2,6,7,8,11,13,14, 26 and 31 are objected to because of the following informalities: In claims 1,2,6,7,8,11,13, and 14 imagable is spelled incorrectly. In claim 14 sensor is spelled incorrectly. In sentence one of claim 26 the 'a' in 'comprises a one or' needs to be deleted. In the third sentence of claim 26 there needs to be the word 'the' or 'said' before 'sensor elements'. In sentence six of claim 31 the 'an' in 'wherein the an in' needs to be deleted.

***Claim Rejections - 35 USC § 112***

4. Claims 1,2,6,7,8,11,13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: "imagable marker properties".

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the second step of this method claim there are many different ways of relating two quantities thus it is not clear what the relationship between position of the sensor device and markers is. In the fourth step of this method claim it is not clear how determine the position of the sensor device based on relating.

*Claim Rejections - 35 USC § 102*

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Scarantino et al. (US Patent 6402689).

Consider claim 1, Scarantino et al. show and disclose a sensor device ((sensor unit) 50” and figure 7), comprising: a sensor element ((sensor element) 50 and figure 7) configured to monitor in vivo a physiological parameter associated with a patient (Column 4 ines 10-18, column 7 lines 34-35, and column 8 lines 52-62); and a plurality of imagable marker properties. It is an inherent property of a sensor used in medical applications to be imaged.

Claims 12-14, 27-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Paltieli (US Patent 6669653).

Consider claim 12, Paltieli shows and discloses a method, comprising: implanting a sensor device in a body ((sensor) 1000, Column 5 lines 39-53, column 6 lines 42-54, and figures 1,10A); and discerning an orientation of the sensor device in the body using an imaging technique (Column 5 lines 55-63 and figure 4A).

Consider claim 13 Paltieli shows and discloses the method of claim 12, wherein the sensor device comprises a plurality of imagable marker properties and wherein discerning comprises imaging the plurality of marker properties (Column 2 lines 38-47, Column 5 lines 38-62, Column 11 lines 49-59, column 12 lines 8-25, and figure 5).

Consider claim 14, Paltieli shows and discloses the method of claim 13, wherein the plurality of imagable marker properties are disposed along a dimension of the sensor device and wherein discerning further comprising displaying each of the plurality of imaged marker properties (Column 4 lines 29-33, column 5 lines 51-54 and figure 5).

Consider claim 27, Paltieli shows and discloses an apparatus, comprising: means for monitoring in vivo at least one physiological parameter of the body ((sensor) 1000, Column 5 lines 39-53, column 6 lines 42-54, and figures 1,10A); and means for identifying a position ((position sensor) PS2, column 5 lines 38-62), of the means for monitoring relative to an in vivo coordinate system with an imaging technique (Column 2 lines 38-47, Column 11 lines 49-59, column 12 lines 8-25, and figure 5).

Consider claim 28, Paltieli shows and discloses the apparatus of claim 27, further comprising means for establishing the in vivo coordinate system (Column 4 lines 9-55).

Consider claim 29 Paltieli shows and discloses the apparatus of claim 28, wherein the means for identifying comprises means for correlating the position of the means for monitoring with the in vivo coordinate system (Column 2 lines 38-48, column 3 lines 1-9, and figures 4A,5)

Consider claim 30, Paltieli shows and discloses the apparatus of claim 27, further comprising means for determining an orientation of the means for monitoring (Column 5 lines 55-63).

Claims 31,32,35 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Holupka et al. (US Patent 5810007).

Consider claims 31,32,35 and 36, Holupka et al. show and disclose a method of imaging a plurality of markers and an in vivo landmark (prostate gland) in a first imaging modality CT (Abstract, column 3 line 53-64 and column 4 lines 13-15, and figures 2,3); correlating a position of the in vivo landmark relative to at least one of the plurality of markers (column 3 lines 61-67 and figure 2); imaging the plurality of markers in a second modality Ultrasound (column 3 line 62), wherein the an in vivo landmark is not imagable in the second modality (column 1 lines 54-56); and determining the position of the an in vivo landmark relative to at least one of the plurality of markers based on the correlating (column 3 lines 61-67).

***Claim Rejections - 35 USC § 103***

6. Claims 2-11,15-17,18,19-21,23,24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scarantino et al. (US Patent 6402689) as applied to claim 1 above, and further in view of Glossop (US Patent 6785571).

Consider claims 2-8, Scarantino et al. show and disclose all features of the current invention (Abstract, Column 8 lines 52-62, Column 24 lines 11-35 and figure 7) except for a plurality of markers disposed along a length of the sensor device in a manner to discern an orientation of the sensor. Glossip shows and discloses an insertable portion for holding a position sensor with fiducial markings disposed along the length of the insertable portion that allow the position, and preferably, the orientation of the insertable portion to be accurately determined with respect to the anatomic body. The fiducial markers can be imaged in at least two imaging modalities. (Abstract, column 3 lines 11-21, column 4 lines 62-67, column 5 lines 3-62, 45-68,



column 6 lines 11-22, column 7 lines 1-10 and figure 2B). It would have been obvious to a person of skill in the art at the time of the invention to modify the sensor unit of Scarantino with these teachings of Glossop to accurately determine the position, and preferably the orientation, of the sensor unit with respect to the anatomical body.

Consider claims 9-10, Scarantino et al. show and disclose the sensor device of claim 4, has a length of 27 mm (Column 21 lines 20-21). It would have been obvious to a person of skill in the art at the time of the invention to decrease the length of the sensor device of Scarantino to improve maneuverability of the device when placing it in the human body and since biosensors are also inherently small.

Consider claim 11, Scarantino et al. show and disclose the sensor device of claim 1 wherein the plurality of imageable marker properties comprises a plurality of markers except for the markers being disposed in the sensor device. It would have been obvious to a person of skill in the art at the time of the invention to modify the unit of Scarantino by placing fiducial markings in the sensor device to accurately determine the position, and preferably the orientation, of the sensor device with respect to the anatomical body using certain imaging modalities.

Consider claims 15-17, 19-21, 24 and 26 Scarantino et al. show and disclose all features of the current invention (Abstract, column 2 lines 39-47, column 8 lines 53-63, column 10 lines 35-51, column 24 lines 11-45, column 25 lines 52-61 and figure 7) except for identifying a position of the sensor device relative to an internal coordinate system using an imaging technique. Glossop shows and discloses an insertable portion for holding a position sensor with fiducial markings disposed along the length of the insertable portion that allow the position, and

preferably, the orientation of the insertable portion to be accurately determined. The fiducial markers can be imaged in at least two imaging modalities. (Abstract, column 3 lines 11-21, column 4 lines 62-67, column 5 lines 3-62, 45-68, column 6 lines 11-22, column 7 lines 1-10 and figure 2B). It would have been obvious to a person of skill in the art at the time of the invention to modify the sensor unit of Scarantino with these teachings of Glossop to accurately determine the position, and preferably the orientation, of the sensor unit with respect to the anatomical body.

Consider claim 18, Scarantino et al. show and disclose the method of claim 15 except for the sensor device having a length less than approximately 26 millimeters. It would have been obvious to a person of skill in the art at the time of the invention to use a sensor device of this size to improve maneuverability of the device when placing it in the human body and since biosensors are also inherently small.

Consider claim 23, Scarantino et al. show and disclose the method of claim 15 except for an internal coordinate system based on a plurality of markers located in the body and wherein identifying comprises identifying the position relative to at least one of the plurality of markers. It would have been obvious to a person of skill in the art at the time of the invention to place a plurality of markers in the body to provide an internal reference frame of physiological interest so the position of the sensor device can be given relative to these regions of interest.

Claims 33-34 and 37-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holupka.

Consider claims 33 and 34, as best understood (112-2 rejection), Holupka et al. show and disclose the method of claim 31, where the in vivo landmark is a sensor device (column 3 line

50-55 and figure 2) comprises at least one of the plurality of markers (column 3 lines 61-67 and figure 2).

Consider claims 37,38,40, and 41, Holupka et al. show and disclose a second imaging modality except for the modality being kV or MV imaging. It is well known in the art that kV imaging and MV imaging provide quality images and excellent localization. It would have been obvious to a person of skill in the art at the time of the invention to use kV imaging or MV imaging as the second imaging modality to achieve quality images with excellent target localization.

Consider claim 39, Holupka et al. show and disclose a first imaging modality except for the modality being magnetic resonance imaging. It would have been obvious to a person of skill in the art at the time of the invention to use magnetic resonance imaging as the first imaging modality since it is well known in the art that using magnetic resonance imaging for the first imaging modality to achieve quality images with excellent target localization.

Consider claim 42, Holupka et al. show and disclose a second imaging modality except for the modality being ultrasound when the first imaging modality is magnetic resonance imaging. It would have been obvious to a person of skill in the art at the time of the invention to use magnetic resonance imaging as the first imaging modality since it is well known in the art that using these imaging techniques in this manner provide high quality images and excellent localization.

**Allowable Subject Matter**

7. Claim 25 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

***Conclusion***

8. Prior art relevant to this patent application but not included in this Office action includes: US Patents (5447154,6208883,6256529,7020512,6611700,6542770) and US Publications (20050059887,20030139669).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn D. Reed whose telephone number is (571)272-9093. The examiner can normally be reached on Monday - Thursday, 6:30 a.m - 5:00 p.m., EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jayprakash Gandhi can be reached on (571)272-9820. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Lynn D Reed  
Examiner  
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JAYPRAKASH GANDHI  
SUPERVISORY PATENT EXAMINER